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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/273,957	03/22/1999	HUAMING WANG	GC477C1	7787

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/15/2001

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/273,957

Applicant(s)

WANG ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sept. 6, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,6-17 and 57-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,6-17 and 57-63 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other:

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The examiner acknowledges the Amendment and Remarks, paper No.12, filed on September 6, 2001. Claims 3, 6-14, and 57-58 have been amended as requested. Claims 1, 2, 4, 5 and 18-56 have been deleted. New claims 59-63 have been added. The title of the application has been changed as requested.

Claims 3, 6-17 and 57-63 are pending in this application are the subject of this Office action.

Detailed Office Action

1. Response to the Remarks to the First Office Action

1.1. Claim objection withdrawals

In the light of the canceling of claim 1 and 2 the objections has been withdrawn.

The objections to the drawings remain still applicable.

1.2. Rejections under 35 USC section 112, first paragraph

The rejections for lack of written description and scope of enablement remain applicable to the amended claims.

1.3. Rejection under 35 USC section 102 (e)

In the light of the cancellation of claims 1, 2, 4, 5 and 56 and amendment to claims 13 and 14, the rejection is withdrawn.

1.4. Double patenting rejection

Provisional obviousness-type and statutory double patenting rejections remains applicable to the amended claims.

2. Objections

The objections to the drawings set forth in the first Office action is still applicable; see the enclosed notice of draft person, form PTO 948. Figure 3 contains errors in description of molecular weight markers: 64 should be 44, 80 should be 30. Formal drawings will be required when the application is allowed.

The objection to the claim set forth in the first Office action is withdrawn because the objected claim has been cancelled.

2.1. Specification

In the previous office action, the examiner did not object to the specification for lack of the necessary reference to the prior applications to which the priority under 35

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USC 120 is claimed. The respective statement should be entered following the title of invention. Also, the present status of all parent applications should be included.

1.3. Claims

The amended claims 12 and 13 are objected to as containing the word "of" after the word pH optimum in line 1. Please correct this typographical error.

2. Rejections

2.1. 35 USC section 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims as filed were not the subject of rejection under 35 USC section 112, second paragraph. However, the amended claims 3, 6-7 and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regard as the invention.

Claims 3, and 6-7 recite the phrase: "wherein said purified enzyme exhibits and increase in apparent molecular weight after boiling." This phrase makes the claim indefinite. Many proteins, when boiled, exhibit a change of conformation and possible aggregation that slow down migration in gels, hence a higher molecular weight.

The examiner suggests recitation of the molecular weights determined before and after boiling.

Claims 3, 6-7 and 10-14 recite the phrase "the color associated with a dye or colored compound" that makes the claims indefinite. Neither the claims nor the specification provide a definite meaning of the term "colored compounds."

The specification is objected to for indefinite description of the term "colored compound" on , page 8, line 24. The Applicants state "As used herein, the term 'colored compound' refers to a substance that adds color to textiles or to substances, which result in the visual appearance of stains. As defined by in Dictionary of Fiber and Textile Technology (Hoechst Celanese Corporation (1999) PO Box 32414, Charlotte NC 28232), a dye is a colored compound that is incorporated into the fiber by chemical reaction, absorption, or dispersion. Examples of dyes include direct Blue dyes, acid Blue dyes, and direct red dyes, reactive Blue and reactive Black dyes. A catalog of commonly used textile dyes is found in Colour Index, 3rd ed. Vol. 1-8. Examples of substances which result in the visual appearance of stains are polyphenols, carotenoids, anthocyanins, tannins, Maillard reaction products, etc."

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The examiner acknowledges the reference of the one skilled in the art to the Colour Index 3rd ed. Vol. 1-8. The examiner also acknowledges examples of **dyes**: "direct Blue dyes, acid Blue dyes, direct red dyes, reactive Blue and reactive Black dyes" and examples of **groups** of chemical compounds used in coloring fibers: "polyphenols, cartenoids, anthocyanins, tannins, Maillard reaction products, etc." However, without specifying the chemical compounds in the claims, the one skilled in the art would not know which chemical compounds to chose.

The use of the language "is capable of modifying dyes selected from the group consisting of: direct blues 14 and 1 (Sigma), direct blue 53 (Fluka), direct blue 98 (Zeneca), acid blue 113 (Aldrich), direct red 28 (Sigma), direct red 21 (Fluka), direct red 79 (Zeneca), reactive blue Cibacron GN_E(Ciba-Geigy), reactive blue Cibacron GN_R (Ciba-Geigy), reactive blue 160 (Zeneca), malvin blue, as well as bleaching tomato stains" would vacate the rejection.

2.2. 35 USC section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2.2.1. Rejections for lack of written description

Although the rejection of claims 1 and dependent claims 2-14 and 56-57 for lack of written description set forth in the previous Office action, paper No 11, has been withdrawn in the light of Applicant's cancellation of claim 1, 2, 4, 5 and 56, and the Applicants arguments, the amended claims 3, 6 and 7-9, 10-14, 15-17 and 57 are still rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3, 6 and 7-9 are drawn to a purified phenol oxidizing enzyme, obtained from the species *Stachybotrys chartarum* and *parvispora*. The term phenol oxidizing defines a generic function including the following enzymatic activities: oxidases [e.g. laccases (EC 1.10.3.2), catechol oxidases (EC 1.10.3.1) and bilirubin oxidases (EC 1.3.3.5)] and peroxidases (EC 1.11.1.7). The specification fails to describe representative species of the phenol oxidizing enzyme as claimed in claims 3, 6-7, by any identifying structural characteristics or properties other than activity of oxidation of aromatic OH group. Given the lack of additional representative species of the phenol oxidizing enzymes as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

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The examiner suggests to recite in the claims, the specific phenol oxidizing activity of the enzyme.

Claims 3, 6-7 and 10-14 recite an extremely large genus of colored compounds catalogued in Colour Index, 3rd ed. Vol. 1-8; see the above objection of the specification. The specification exemplifies colored compounds, but fails to describe structural characteristics of colored compounds that are oxidized by the claimed enzyme. There is no disclosure of any particular relationship between the ability of the claimed enzyme to oxidize a colored compound and the structure of the colored compound. The examiner concludes that, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 15 and 17 are directed to a purified phenol oxidizing enzyme obtainable from the genus *Stachybotrys*, comprising *S. parvispora*, *S. chartarum*, *S. kampelensis*, *S. theobromae*, *S. bisbyi*, *S. cylindrospora*, *S. dichroa*, *S. oenanthae* and *S. nilagerica*, having at least 65% identity to the phenol oxidizing enzyme of SEQ ID NO:2. The disclosure is silent about a phenol oxidizing enzyme having at least 65 % identity to the phenol oxidizing enzyme of *Stachybotrys chartarum* that was obtained from any of the enumerated species. Because of the lack of written description of the claimed enzyme the examiner concludes that Applicants were not in possession of the claimed invention when the application was filed.

Claim 57 is directed to an enzyme composition comprising a phenol oxidizing enzyme that has at least 65% identity to the phenol oxidizing enzyme having the amino acid sequence as disclosed in SEQ ID NO:2. The claim is directed to a large genus of the phenol oxidizing enzymes from any natural or man-made sources. The disclosure does not set forth any enzyme that is a phenol oxidizing enzyme and has at least 65% identity to the *Stachybotrys chartarum* enzyme of SEQ ID NO:2. Therefore, the examiner concludes that Applicants were not in the possession of the claimed invention when the application was filed.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification lacks a sufficient written description for enablement based on deposit requirement.

The invention appears to employ new *Stachybotrys chartarum* and *Stachybotrys parvispora* cell strains. Since the cell strains are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. It is not apparent if said cell strains are readily available to the public. It is noted that the applicant has deposited the strain of *Stachybotrys chartarum* (MUCL accession number 38898) and *parvispora* (MUCL accession number 38996), but there is no indication in the specification as to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or

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declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. § 1.801-1.809, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

- (1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;
- (3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (4) the deposit will be replaced if it should ever become inviable.

Claims 6-9 and 59-63 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

2.2.2. Rejection for scope of enablement

In the light of the Applicants' arguments and amendments to the claims the rejection under 35 USC 112, first paragraph, for lack of enablement for the enzyme isolated from the *Stachybotrys* genus, set forth in the previous Office Action, paper No.11, is withdrawn. The examiner agrees Applicants characterized the structure and biochemical feature of the enzyme from *Stachybotrys chartarum* and biochemical features of the enzyme from *Stachybotrys parvispora* in a manner that enables the one skilled in the art to make the invention.

However, the amended Claim 3, 6-7, and 10-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for direct blues 14 and 1 (Sigma), direct blue 53 (Fluka), direct blue 98 (Zeneca), acid blue 113 (Aldrich), direct red 28 (Sigma), direct red 21 (Fluka), direct red 79 (Zeneca), reactive blue Cibacron GN_E (Ciba-Geigy), reactive blue Cibacron GN_R (Ciba-Geigy), reactive blue 160 (Zeneca), malvin blue and indefinite number of dyes of the tomato stains, does not reasonably provide enablement for all the colored compound and dyes as defined on page 8, line 23 of the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broader than the enablement provided by the disclosure with regard to the huge number of dyes broadly encompass by the claims. The scope of the

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claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, an additional undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses any dye belonging to that listed in Colour Index, 3rd ed. Vol. 1-8. While performing oxidation reaction using a dye and an enzyme is well known in the relevant art and skills of the artisans are highly developed, screening of an extremely large number of known dyes from the genus of colored compounds that are catalogued in Colour Index, 3rd edition, is not within the realm of routine experimentation.

The working examples provide the guidance only for the direct blues 14 and 1 (Sigma), direct blue 53 (Fluka), direct blue 98 (Zeneca), acid blue 113 (Aldrich), direct red 28 (Sigma), direct red 21 (Fluka), direct red 79 (Zeneca), reactive blue Cibacron GN_E (Ciba-Geigy), reactive blue Cibacron GN_R (Ciba-Geigy), reactive blue 160 (Zeneca), malvin blue and indefinite number of days of the tomato stains.

The examiner finds that one skilled in the art would require additional guidance such as defining more species of the extremely large genus of chemicals. Without such guidance, the experimentation left to those skilled in the art is improperly extensive and undue.

2.3 Double patenting

The Applicants defer any further discussion on the double patenting rejections set forth in the first Office action, paper No. 1, until there is agreed upon patentable subject matter in the present application, the double patenting rejection remains, therefore, applicable.

2.3.1. Nonstatutory

Claims 15-17 and amended claims 57-58 are still provisionally rejected under the judicially created doctrine of double patenting over claims 1, 2, 3, of copending Application No. 09/218,702 (702) filed on December 12, 1298.

2.3.2 Statutory

Rejection of claim 16 directed to the same invention as that of claim 3 of copending Application No. 09/218,702 remains applicable.

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3. Allowable subject matter

No claim is in condition for allowance, however, the phenol oxidizing enzyme of *Stachybotrys parvispora* claimed in the instant application is free of prior art. The phenol oxidizing enzyme of *Stachybotrys chartarum* is free of prior art, but the subject of the above provisional double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

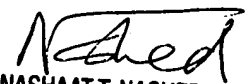
If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Assistant Patent Examiner



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PRIMARY EXAMINER